Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*



| Complete if Known | |
|---|---|
| Application Number | 10/652,814 |
| Filing Date | August 29, 2003 |
| First Named Inventor | Unger |
| Art Unit | 1636 |
| Examiner Name | Riggins, P. |
| Attorney Docket Number | 3193.01US03 |

Sheet 1 of 2

## U.S. PATENT DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Document Number Number-Kind Code[2] (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document |
|---|---|---|---|---|
| IP | | US-5,492,814 | 02-20-1996 | Weissleder |
| IP | | US-6,255,457 | 07-03-2001 | Schnitzer |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |

## FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | T[6] |
|---|---|---|---|---|---|
| IP | | WO 99/29349 | 06-17-1999 | Behr et al. | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

| EXAMINER SIGNATURE | /Ileana Popa/ | DATE CONSIDERED | 06/02/2006 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

| Substitute for form 1449/PTO<br><br>INFORMATION DISCLOSURE STATEMENT BY APPLICANT<br>*(Use as many sheets as necessary)* | | | | *Complete if Known* | |
|---|---|---|---|---|---|
| | | | | Application Number | 10/652,814 |
| | | | | Filing Date | August 29, 2003 |
| | | | | First Named Inventor | Unger |
| | | | | Art Unit | 1636 |
| | | | | Examiner Name | Riggins, P. |
| Sheet | 2 | of | 2 | Attorney Docket Number | 3193.01US03 |

NON PATENT LITERATURE DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T[2] |
|---|---|---|---|
| IP | | ANDERSON, "The Caveolae Membrane System", Ann. Rev. Biochem., 67:199-225 (1998). | |
| IP | | FENG ET AL., "Vesiculo-Vacuolar Organelles and the Regulation of Venule Permeability to Macromolecules by Vascular Permeability Factor, Histamine, and Serotonin", J. Exp. Med., 183:1981-1986 (1996). | |
| IP | | VARGA ET AL., "Receptor-mediated Targeting of Gene Delivery Vectors; Insights from Molecular Mechanisms for Improved Vehicle Design", Biotechnology and Bioengineering, 70(6): 593-605 (2000). | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

| EXAMINER SIGNATURE | /Ileana Popa/ | DATE CONSIDERED | 06/02/2006 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*



| Complete if Known | |
|---|---|
| Application Number | 10/652,814 |
| Filing Date | August 29, 2003 |
| First Named Inventor | Unger |
| Art Unit | 1636 |
| Examiner Name | Unknown |
| Attorney Docket Number | 3193.01US03 |

| Sheet | 1 | of | 1 |
|---|---|---|---|

## NON PATENT LITERATURE DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T[2] |
|---|---|---|---|
| IP | | AL-MOUSA, ET. AL, (1999) J Pharm Pharmacol 51(supplement):178, "Evidence for the role of caveolae in gene delivery." | |
| IP | | LEWIN ET. AL, (2000) Nature 18:410-414, "Tat peptide-derivatized magnetic nanoparticles allow in vivo tracking and recovery of progenitor cells." | |
| IP | | MATVEEV ET. AL, (2001) Adv Drug Deliv Rev 49:237-250,"The role of caveolae and caveolin in vesicle-dependent and vesicle-independent trafficking." | |
| IP | | WOLFF ET. AL, (1992) J Cell Sci 103:1249-59, "Expression of naked plasmids by cultured myotubes and entry of plasmids into T tubules and caveolae of mammalian skeletal muscle." | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

| EXAMINER SIGNATURE | /Ileana Popa/ | DATE CONSIDERED | 06/02/2006 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

| *Complete if Known* | |
|---|---|
| Application Number | 10/652,814 |
| Filing Date | August 29, 2003 |
| First Named Inventor | Unger |
| Art Unit | 1636 |
| Examiner Name | Unknown |
| Attorney Docket Number | 3193.01US03 |

| Sheet | 1 | of | 8 |
|---|---|---|---|

## U.S. PATENT DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Document Number Number-Kind Code[2] (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document |
|---|---|---|---|---|
| IP | | US-4,107,288 | 08-15-1978 | Oppenheim et al. |
| | | US-4,177,177 | 12-04-1979 | Vanderhoff et al. |
| | | US-4,913,908 | 04-03-1990 | Couvreur et al. |
| | | US-4,920,016 | 04-24-1990 | Allen et al. |
| | | US-4,937,119 | 06-26-1990 | Nikles et al. |
| | | US-4,968,350 | 11-06-1990 | Bindschaedler et al. |
| | | US-5,116,507 | 05-14-1996 | N'Guyen et al. |
| | | US-5,133,908 | 07-28-1992 | Stainmesse et al. |
| | | US-5,145,684 | 09-08-1992 | Liversidge et al. |
| | | US-5,384,133 | 01-24-1995 | Boyes et al. |
| | | US-5,439,686 | 08-08-1995 | Desai et al. |
| | | US-5,498,421 | 03-12-1996 | Grinstaff et al. |
| | | US-5,503,851 | 04-02-1996 | Mank et al. |
| | | US-5,578,709 | 11-26-1996 | Woiszwillo |
| | | US-5,629,021 | 05-13-1997 | Wright |
| | | US-5,639,473 | 06-17-1997 | Grinstaff et al. |
| | | US-5,639,480 | 06-17-1997 | Bodmer et al. |
| IP | | US-5,648,095 | 07-15-1997 | Illum et al. |

## FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | T[6] |
|---|---|---|---|---|---|
| IP | | EP0860167 | 08-26-1998 | Gurny | |
| IP | | WO00/47130 | 08-17-2000 | Devore | |
| IP | | WO88/08011 | 10-20-1988 | Bindschaedler et al. | |
| IP | | WO97/03702 | 02-06-1997 | Mathiowitz et al. | |
| | | | | | |

| EXAMINER SIGNATURE | /Ileana Popa/ | DATE CONSIDERED | 06/02/2006 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

| Substitute for form 1449/PTO<br><br>INFORMATION DISCLOSURE STATEMENT BY APPLICANT<br>*(Use as many sheets as necessary)* | | | | *Complete if Known* | |
|---|---|---|---|---|---|
| | | | | Application Number | 10/652,814 |
| | | | | Filing Date | August 29, 2003 |
| | | | | First Named Inventor | Unger |
| | | | | Art Unit | 1636 |
| | | | | Examiner Name | Unknown |
| Sheet | 2 | of | 8 | Attorney Docket Number | 3193.01US03 |

## U.S. PATENT DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Document Number<br>Number-Kind Code[2] *(if known)* | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document |
|---|---|---|---|---|
| IP | | US-5,648,097 | 07-15-1997 | Nuwayser |
| | | US-5,736,156 | 07-07-1998 | Burke |
| | | US-5,759,582 | 06-02-1998 | Leong et al. |
| | | US-5,846,561 | 12-08-1998 | Margalit |
| | | US-5,858,398 | 01-12-1999 | Cho |
| | | US-5,874,111 | 02-23-1999 | Maitra et al. |
| | | US-5,916,803 | 06-29-1999 | Sedlacek et al. |
| | | US-5,962,427 | 10-05-1999 | Goldstein et al. |
| | | US-5,962,566 | 10-05-1999 | Grandfils et al. |
| | | US-5,985,832 | 11-16-1999 | Roodman et al. |
| | | US-5,990,089 | 11-23-1999 | Szoka Jr. et al. |
| | | US-6,033,645 | 03-07-2000 | Unger |
| | | US-6,051,258 | 04-18-2000 | Kantor |
| | | US-6,136,295 | 10-24-2000 | Edwards et al. |
| | | US-6,139,870 | 10-31-2000 | Verrecchia |
| | | US-6,143,037 | 11-07-2000 | Goldstein et al. |
| | | US-6,143,211 | 11-07-2000 | Mathiowitz et al. |
| | | US-6,146,663 | 11-14-2000 | Bissery et al. |
| IP | | US-6,165,440 | 12-26-2000 | Esenaliev |

## FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Foreign Patent Document<br>Country Code[3] Number[4] Kind Code[5] *(if known)* | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | T[6] |
|---|---|---|---|---|---|
| IP | | WO98/43664 | 10-08-1998 | Kim et al. | |
| IP | | WO99/00113 | 01-07-1999 | Desai et al. | |
| IP | | WO99/33558 | 07-08-1999 | Quintanar-Guerrero et al. | |
| | | | | | |

| EXAMINER SIGNATURE | /Ileana Popa/ | DATE CONSIDERED | 06/02/2006 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

| Substitute for form 1449/PTO | | | | Complete if Known | |
|---|---|---|---|---|---|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)* | | | | Application Number | 10/652,814 |
| | | | | Filing Date | August 29, 2003 |
| | | | | First Named Inventor | Unger |
| | | | | Art Unit | 1636 |
| | | | | Examiner Name | Unknown |
| Sheet | 3 | of | 8 | Attorney Docket Number | 3193.01US03 |

## U.S. PATENT DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Document Number Number-Kind Code[2] (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document |
|---|---|---|---|---|
| IP | | US-6,165,988 | 12-26-2000 | Noe et al. |
| IP | | US-6,177,103 | 01-23-2001 | Pace et al. |
| IP | | US-6,197,346 | 03-06-2001 | Mathiowitz et al. |
| IP | | US-6,322,805 | 11-27-2001 | Kim et al. |
| IP | | US-6,322,805 | 11-27-2001 | Kim et al. |
| IP | | US-6,372,714 | 04-16-2002 | Tanaka et al. |
| IP | | US-6,632,671 | 10-14-2003 | Unger |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |
| | | US- | | |

## FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | T[6] |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

| EXAMINER SIGNATURE | /Ileana Popa/ | DATE CONSIDERED | 06/02/2006 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

| Substitute for form 1449/PTO | | | | Complete if Known | |
|---|---|---|---|---|---|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)* | | | | Application Number | 10/652,814 |
| | | | | Filing Date | August 29, 2003 |
| | | | | First Named Inventor | Unger |
| | | | | Art Unit | 1636 |
| | | | | Examiner Name | Unknown |
| Sheet | 4 | of | 8 | Attorney Docket Number | 3193.01US03 |

NON PATENT LITERATURE DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T[2] |
|---|---|---|---|
| IP | | AKHTAR, ET AL., (2000):The delivery of antisense therapeutics. Advanced Drug Delivery Reviews (44): 3-21. | |
| | | ASH, ET AL., Handbook of Industrial Surfactants, Gower Publishing Co. (1993), pp. 885-905. | |
| | | BALLY ET AL., (1999): Biological barriers to cellular delivery of lipid-based DNA carriers, Advanced Drug Delivery Reviews (38):291-315. | |
| | | BARRY, B. W., Dermatological Formulations: Percutaneous Absorption, pages 127-531. | |
| | | BRAND ET AL., (2000): Transdermal delivery of antisense compounds. Advanced Drug Delivery Reviews (44) 51-57. | |
| | | BRANNON-PEPPAS (1997): Polymers in Controlled Drug Delivery. Medical Plastics and Biomaterials Magazine: 1-17. | |
| | | BRONAUGH, ET AL., Editors, Percutaneous Absorption Drugs-Cosmetics-Mechanisms-Methodology, 3rd Ed., (1999), pp. 177-193; 597-613 and 879-886. | |
| | | CALVO, ET AL., Comparitive in vitro Evaluation of Several Colloidal Systems, Nanoparticles, Nanocapsules, and Nanoemulstions, as Ocular Drug Carriers, Journal of Pharmaceutical Sciences, (1995), pp. 530-536. | |
| | | CALVO, ET AL, Evaluation of Cationic Polymer-Coated Nanocapsules as Ocular Drug Carriers, International Joural of Pharmaceutics (1997), pp. 41-50. | |
| | | DAMAGE ET AL., Intestinal Absorption of PLAGA microspheres in the rat, (1996) J. Anat, pp. 491-501. | |
| | | DEAN, Lange's Handbook of Chemistry, 15th Edition, pages 1.74-1.343, 10.69-10.73. | |
| IP | | DOKKA ET AL., (2000): Novel non-endocytic delivery of antisense oligonucleotides, Advanced Drug Delivery Reviews (44): 35-49. | |

| EXAMINER SIGNATURE | /Ileana Popa/ | DATE CONSIDERED | 06/02/2006 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

| Substitute for form 1449/PTO | | | | Complete if Known | |
|---|---|---|---|---|---|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)* | | | | Application Number | 10/652,814 |
| | | | | Filing Date | August 29, 2003 |
| | | | | First Named Inventor | Unger |
| | | | | Art Unit | 1636 |
| | | | | Examiner Name | Unknown |
| Sheet | 5 | of | 8 | Attorney Docket Number | 3193.01US03 |

NON PATENT LITERATURE DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T[2] |
|---|---|---|---|
| IP | | GAUR ET AL., (2000): Biodistribution of fluoresceinated dextran using novel nanoparticles evading reticuloendothelial system, International Journal of Pharmaceutics (2002):1-10. | |
| | | GENNARO, Remington: The Science and Practice of Pharmacy, 20th Ed., Lippincott Williams & Wilkins, pp. 288-334; 721-752; 836-857 and 903-929. | |
| | | GERNER ET AL., (1998): Similarity Between Nuclear Matrix Proteins of Various Cells Revealed by an Improvecd Isolation Method. Journal of Cellular Biochemistry (71) 363-374. | |
| | | GOLAN ET AL., (1999): DNA Toroids: Stages in Condensation. Biochemistry (38): 14069-14076. | |
| | | GOPFERICH, (1995): Polymer Degradation and Erosion: Mechanisms and Applications. Eur. J. Pharm. Biophar. 42(1):1-11. | |
| | | JANES, ET AL., Polysaccharide Colloidal Particles as Delivery Systems for Macromolecules, Advanced Drug Delivery Reviews (2001), pp. 83-97. | |
| | | KATOAKA, ET AL., Block Copolymer Micelles for Drug Delivery: Design, Characterization and Biological Significance, Advanced Drug Delviery Reviews (2001), pp. 113-131. | |
| | | KAWASHIMA, Nanoparticle Systems for Improved Drug Delivery, Advanced Drug Delivery Reviews (2001), pp. 1-2. | |
| | | KIBBE, ARTHUR H. EDITOR, (1986): Handbook of Pharmaceutical Excipients, American Pharmaceutical Association, Third Edition, pages 94-95, 117-120. | |
| | | KREUTER, Mini-review: Nanoparticles and Microparticles for Drug and Vaccine Delivery, J. Anat. (1996), pp. 503-505. | |
| | | GOLAN ET AL., (1999): DNA Toroids: Stages in Condensation. Biochemistry (38): 14069-14076. | |
| IP | | GOPFERICH, (1995): Polymer Degradation and Erosion: Mechanisms and Applications. Eur. J. Pharm. Biophar. 42(1):1-11. | |

| EXAMINER SIGNATURE | /Ileana Popa/ | DATE CONSIDERED | 06/02/2006 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

| Substitute for form 1449/PTO | | | | Complete if Known | |
|---|---|---|---|---|---|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)* | | | | Application Number | 10/652,814 |
| | | | | Filing Date | August 29, 2003 |
| | | | | First Named Inventor | Unger |
| | | | | Art Unit | 1636 |
| | | | | Examiner Name | Unknown |
| Sheet | 6 | of | 8 | Attorney Docket Number | 3193.01US03 |

NON PATENT LITERATURE DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T[2] |
|---|---|---|---|
| IP | | JANES, ET AL., Polysaccharide Colloidal Particles as Delivery Systems for Macromolecules, Advanced Drug Delivery Reviews (2001), pp. 83-97. | |
| | | KATOAKA, ET AL., Block Copolymer Micelles for Drug Delivery: Design, Characterization and Biological Significance, Advanced Drug Delviery Reviews (2001), pp. 113-131. | |
| | | KAWASHIMA, Nanoparticle Systems for Improved Drug Delivery, Advanced Drug Delivery Reviews (2001), pp. 1-2. | |
| | | KIBBE, ARTHUR H. EDITOR, (1986): Handbook of Pharmaceutical Excipients, American Pharmaceutical Association, Third Edition, pages 94-95, 117-120. | |
| | | KREUTER, Mini-review: Nanoparticles and Microparticles for Drug and Vaccine Delivery, J. Anat. (1996), pp. 503-505. | |
| | | KREUTER, Nanoparticulate Systems for Brain Delivery of Drugs, Advanced Drug dleivery Reviews (2001), pp. 65-81. | |
| | | KREUTER, Nanopaticles-Preparation and Applications, Microcapsules and Nanoparticles in Medicine and Pharmacy, pp. 125-148. | |
| | | KREUTER, Nanopatricle-Based Drug Delivery Systems, Journal of Controlled Release (19914), pp. 169-176. | |
| | | LAMAZE, ET AL., The Emergence of Clathrin-Independnet Pinocytic Pathways, Current Opinion in Cell Biology (1995), pp. 573-580. | |
| | | LI ET AL., (2000): Nonviral gene therapy: promises and challenges, Gene Therapy (7): 31-34. | |
| | | LIBERMAN, ET AL., (1996): Pharmaceutical Dosage Forms: Disperse Systems, Vol. 2, Second Edition, pages 1-109. | |
| IP | | LIDE, EDITOR IN CHIEF, CRC Handbook of Chemistry and Physics: A Ready-Reference Book of Chemical and Physical Data, Chemical Rubber Publishing Co, 81st, (1922), pp. 7-7 to 7-9; 16-10 to 16-11; 16-43 to 16-47; Appendix. | |

| EXAMINER SIGNATURE | /Ileana Popa/ | DATE CONSIDERED | 06/02/2006 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

| Substitute for form 1449/PTO | | | | Complete if Known | |
|---|---|---|---|---|---|
| | | | | Application Number | 10/652,814 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)* | | | | Filing Date | August 29, 2003 |
| | | | | First Named Inventor | Unger |
| | | | | Art Unit | 1636 |
| | | | | Examiner Name | Unknown |
| Sheet | 7 | of | 8 | Attorney Docket Number | 3193.01US03 |

NON PATENT LITERATURE DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T[2] |
|---|---|---|---|
| IP | | MODLIN, (2000): A toll fro DNA vaccines. Nature (408): 659-660. | |
| | | MULLER ET AL., Nanosuspensions as Particulae Drug Formulations in Therapy Rationale for Development and What We Can Expect for the Future, Advanced Drug Delviery Reviews (2001), pp. 3-19. | |
| | | NISHIOKA ET AL., Lymphatic Targeting with Nanoparticulate System, Advanced Drug Delivery Reviews (2001), pp. 55-64. | |
| | | NOONBERG, ET AL., (1993): Characteristics of Oligonucleotide Uptake in Human Keratinocyte Cultures. The Jouranal of Invenstigative Dermatology (101): 727-731. | |
| | | Perry's Chemical Engineers' Handbook, (1934), 7th Ed. pp. 2-24 to 2-47. | |
| | | PINTO, ET AL., Pellets as carriers of solid lipid nanoparticles (SLN) for oral administration of Drugs, Pharmazie (1999), pp. 506-509. | |
| | | QUINTANAR-GUERRERO ET AL., (1998): Preparation Techniques and Mechanisms of Formation of Biodegradable Nanoparticles from Performed Polymers. Drug Development and Industrial Pharmacy, 24(12): 1113-1128. | |
| | | ROLLAND, (1998): From Genes to Gene Medicines: Recent Advances in Nonviral Gene Delivery. Critical Reviews in Tsherapeutic Drug Carrier Systems 15(2):143-198. | |
| | | SAKUMA ET AL., Design of Nanoparticles Composed of Graft Copolymers for Oral Peptide Delivery, Advanced Drug Delivery Reviews (2001), pp. 21-37. | |
| | | SCHMIDT, ET AL., Incorporation of Polymeric Nanoparticles into Solid Dosage Forms, Journal of Controlled Release (1997), pp. 115-125. | |
| | | Sigma Company Catalog, Sigma Biochemical and Reagents For Life Science Research, St. Louis, MO. p 1918. | |
| IP | | SMITH, ET AL, Percutaneous Penetration Enhancers, (1995), pp. 1-20. | |

| EXAMINER SIGNATURE | /Ileana Popa/ | DATE CONSIDERED | 06/02/2006 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

| Substitute for form 1449/PTO | | | | Complete if Known | |
|---|---|---|---|---|---|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)* | | | | Application Number | 10/652,814 |
| | | | | Filing Date | August 29, 2003 |
| | | | | First Named Inventor | Unger |
| | | | | Art Unit | 1636 |
| | | | | Examiner Name | Unknown |
| Sheet | 8 | of | 8 | Attorney Docket Number | 3193.01US03 |

NON PATENT LITERATURE DOCUMENTS

| EXAMINER INITIAL* | Cite No.[1] | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T[2] |
|---|---|---|---|
| IP | | TAKEUCHI ET AL., Mucoadhesive Nanoparticle Systems for Peptide Drug Delivery, Advanced Drug Delivery Reviews (2001), pp. 39-54. | |
| IP | | VILE, ET AL., Millenium Review: Cancer Gene Therapy: Hard Lessons and New Courses, Gene Therapy, pp. 2-8. | |
| IP | | YUAN ET AL., (1994): Microvascular Permeability and Interstitial Penetration of Sterically Stabilized (stealth) Liposomes in a Human Tumor Xenograft. Cancer Research (54) 3352-3356. | |
| IP | | ZHANG ET AL., (1997): Comparison of Integrins in Human Skin, Pig Skin, and Perfused Skin: An In Vitro Skin Toxicology Model. Journal of Appliced Toxicology 17(4): 247-253. | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

| EXAMINER SIGNATURE | /Ileana Popa/ | DATE CONSIDERED | 06/02/2006 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*